

Amendment
Serial No. 10/506,980
Attorney Docket No. 062221

AMENDMENTS TO THE DRAWINGS

The attached replacement sheets of drawings include changes to Figs. 1 and 4-7. New Figures 6(b) and 8 are added herein. No new matter has been added.

REMARKS

Claims 21-40 are pending in the present application and are rejected. Claims 21-30 and 32-40 are herein amended.

New Figures

Applicants herein add new Figures 6(b) and 8. Figure 6(b) represents the auto-adjustment of Example 2, discussed at page 13, lines 18-31. Figure 8 represents the relationship between Frequency Shift Keying (FSK) modulator and the voltage controlled current source, discussed at page 9, lines 5-14. This is also supported by the text of provisional application No. 60/362,441 at lines 391-412. Since these new Figures are fully supported by the text of the original specification, no new matter has been added in accordance with MPEP §608.04.

Applicants' Response to the Drawing Objections

The drawings are objected to for several reasons. First, the Office Action states that the drawings must show every feature of the invention specified in the claims. The Office Action notes that the first tube extremity, second tube extremity, the mask, the filter, the memory, the comparator, the switch and the frequency shift keying modulator must be shown.

With respect to the first and second extremities of the tube, Applicants respectfully submit that these are illustrated, as reference characters 13 and 14, respectively, in amended in Figure 1. With regard to the mask, Applicants submit that this is illustrated as element 15 in

Amendment
Serial No. 10/506,980
Attorney Docket No. 062221

amended Figure 1. With regard to the filter, this is illustrated as element 22 in amended Figure 1.

No new matter has been added.

Please see the discussion below regarding memory 120. With regard to the frequency shift keying modulator, please see new Figure 8. The switch is illustrated in amended Figure 7. Additionally, please note that the “comparator” is no longer recited in the claims.

The Office Action also objects to the drawings because they do not illustrate the reference characters d1, d2, t1, t2 and t4, which are discussed in the specification. As noted above, Applicants herein add new Figure 6(b). In Figure 6(b), d1 and d2 represent slopes of the function represented in the figure at time intervals [t1-t2] and [t3-t4], respectively.

The Office Action also objects to the drawings because they include reference characters not mentioned in the specification. These include 22, 35, 37, 38, 39, C1, K, R, 31, 102, 104, 106, 108, 112, 114, 116, 120, 122, 130, 132, t15, t16, 17, Dp and Ek.

In response, Applicants respectfully note that reference character 22 represents the filter in Figure 1. See amended paragraph [0035]. The following sentence was added to the description in paragraph [0035]:

...When at least one filter 22 is placed at one tube's extremity, the control unit 2 is able to calculate the airflow at the second extremity of the tube from the measured pressures PM and PB and from the airflow resistance coefficient KT of said tube and from the airflow resistance coefficient KF of said filter....

This sentence recites the features of claim 2 of the PCT application as filed. No new matter has been added.

Applicants respectfully note that reference character 31 refers to a Pulse Width Modulation (PWM). Please see amended paragraph [0035]. No new matter has been added.

Next, Applicants respectfully note that reference character 110 represents the estimation module, reference character 120 represents the memory which stores clinician settings, reference character 130 represents the inspiration/expiration computation, reference characters 102 and 104 represent outputs, reference character 106 refers to a pressure control loop, reference character 116 represents the data of tube coefficient K_T , and reference characters 112 and 114 refer to data of the first and second pressures P_M and P_B . See amended paragraph [0070] and Figure 5. No new matter has been added.

With respect to reference characters 35, 37 and 39, these reference characters have been deleted from amended Figure 4. With respect to reference character t_{15} , this reference character has been deleted from amended Figure 6. With respect to reference character 108, this reference character has been deleted from amended Figure 5. Thus, these reference numbers are no longer described in the specification.

Applicants respectfully note that reference character 38 refers to a subtractor. Please see amended paragraph [0060]. No new matter has been added.

With respect to reference characters C1, K and R, Applicants respectfully submit that one of ordinary skill in the art would understand that K and R are resistances contained within analog subtractor 34. Additionally, one having ordinary skill in the art would recognize that C1 is a capacitance.

Applicants respectfully note that reference characters t16 and t17 are now included in the specification. See amended paragraph [0078]. No new matter has been added.

With respect to reference characters Dp and Ek, these are mentioned in the description. In particular, Dp is the persistence delay mentioned at page 13, line 2 of the original specification. Ek is the parameter mentioned in particular at page 13, line 5 of the original specification. Accordingly, Applicants respectfully request that the objections to the drawings be withdrawn.

Applicants' Response to Objections to the Specification

The specification is objected to due to a series of informalities. Applicants herein amend the specification to correct these informalities, and other informalities discovered upon review of the specification. Additionally, the Office Action also identifies several variables without identifying what they represent. Specifically, the Office Action cites PI, PE, PWM and AVP as not being identified. In response, Applicants note that PI is "inspiration pressure", PE is "expiration pressure." and PWM is "pulse width modulation." See amended paragraph [0070]. Additionally, Applicants note that AVP is "average pressure value." See amended paragraph [0075]. No new matter has been added. Favorable reconsideration is respectfully requested.

Applicants' Response to Claim Objections

Claims 21, 23, 25, 30, 32, 35, 37 and 40 were objected to. The Office Action identifies a series of informalities regarding the wording of the claims. In response, Applicants herein make

Amendment
Serial No. 10/506,980
Attorney Docket No. 062221

significant amendments to the claims in order to improve their form, clarity and consistency.

Please see the amended claims. Favorable reconsideration is respectfully requested.

Applicants' Response to Claim Rejections under 35 U.S.C. § 112

Claims 21-40 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Specifically, the Office Action states that it is unclear what pressure PM and pressure PB represent, that it is unclear what the values PM(J) and PB(J) represent. Next, the Office Action states that “said comparator” lacks antecedent basis in claim 34. Finally, the Office Action states that it is unclear what “steps 5 to 6” are referring to.

In response, Applicants herein make significant amendments to the claims in order to improve their clarity and consistency. Applicants note that the limitation “PM at said first tube extremity” has been deleted from the independent claims. This is due to the fact that the first pressure sensor does not necessarily need to be positioned at the first extremity of the tube (where the mask or calibrating shell is connected). Thus, references to PM and PB are deleted from the claims and replaced by “first pressure” and “second pressure.”

Furthermore, Applicants note that the apparatus of the invention should be calibrated before use. In order to calibrate an apparatus according to the invention, a shell is used. However, at that time, a mask is not attached to the apparatus. Once calibrated, the shell is removed and a mask is added for treating the patients. Accordingly, the claims are amended to

Amendment
Serial No. 10/506,980
Attorney Docket No. 062221

recite “a calibration shell” for improved clarity. In view of the above comments, Applicants respectfully submit that the amended claims are sufficiently definite. Favorable reconsideration is respectfully requested.

Applicants’ Response to Claim Rejections under 35 U.S.C. § 103

Claims 21-24, 29-34, 37 and 38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson et al. (US 6,066,101) in view of Berthon-Jones (US 6,152,129).

It is the position of the Office Action that Johnson discloses the invention as claimed, with the exception of airflow being generated by a blower or offset compensation means. The Office Action relies upon Berthon-Jones to provide this teaching.

In response, Applicants respectfully submit that the claims, as amended, are not disclosed or suggested by the combination of Johnson and Berthon-Jones. Johnson is directed at an airflow perturbation device comprising a mouthpiece, a barrel 10, and a segmented wheel 5. Barrel 10 includes pressure taps 3 and 3a. Pressure taps 3 and 3a are connected, with pressure transducer 2 disposed in the connecting passage. Additionally, pressure transducer 4 is disposed between pressure tap 3 and the outside air. See column 9, lines 15-19. Segmented wheel 5 includes open segments 5b and blocked segments 5a, and is driven by a belt 7 connected to a motor 6.

Berthon-Jones is directed at an apparatus for determining leak and respiratory airflow. The apparatus includes a nose mask 12, air delivery hose 20, and blower 14. Two sensor hoses 28 and 30 are attached to pneumotachograph 24. Pressure sensor 32 detects the pressure differential between those pressures detected from hoses 28 and 30 and outputs delivery pressure

signal p_m . Meanwhile, a second pressure sensor 34 is attached to hose 28 only, and outputs flow signal f_d .

In response, Applicants respectfully submit that the combination of references does not disclose or suggest the invention as recited in the amended claims. Specifically, the combination of references does not disclose a first pressure sensor and a second pressure sensor for measuring a pressure at the air output of the blower. Neither Johnson nor Berthon-Jones discloses or suggest a pressure measurement at the output of a blower.

Additionally, the combination of Johnson and Berthon-Jones does not disclose, or even suggest, an offset compensation means for compensating the possible difference of gauging between the pressure sensors. Leak flow calculations (Berthon-Jones, column 4, lines 40-45) should not be interpreted as offset compensation means. In the specification as filed, on page 7, lines 14-16, it is disclosed that:

...By offset it is meant that the constant which corresponds to the difference between the pressure measured by one sensor and the absolute value of pressure...

According to the invention, sensors offsets (that drift during time) are compensated and the needed amplification is allowed without errors that have an impact on treatments. This offset is recited in claims 22, 23 and 25.

Additionally, Applicants note that the sensors that are used in the apparatus of the invention are low-cost sensors that are accurate for measurement of low airflow values but present a drift that may change drastically from one sensor to another. Thus, pressure measurements made using such sensors are not so precise and should not be amplified for a later

Amendment
Serial No. 10/506,980
Attorney Docket No. 062221

calculation that impact the airflow applied to patients. This is the reason why, according to the invention, offset compensation means are used before signal amplification. Due to this offset compensation means, the Applicants have successfully commercialized an apparatus according to the invention which is low-cost, smaller, but which still precisely computes the sensors' pressure data to provide efficient treatments. Favorable reconsideration is respectfully requested.

Claims 25-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson et al. and Berthon-Jones as applied to claim 23 above and further in view of Hoffman (US 6,287,264).

It is the position of the Office Action that the combination of Johnson and Berthon-Jones discloses the invention as claimed, with the exception of the operation of the offset compensation means and the microcontroller. The Office Action relies upon Hoffman to provide this teaching. In response, Applicants respectfully submit that claims 25-27 are patentable due to their dependency on independent claim 23, which Applicants submit is patentable for at least the reasons discussed above. Favorable reconsideration is respectfully requested.

Claim 28 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson et al. and Berthon-Jones as applied to claim 23 above and further in view of Orr et al. (US 2006/0117856).

It is the position of the Office Action that the combination of Johnson and Berthon-Jones discloses the invention as claimed, with the exception of a filter. The Office Action relies on Orr

Amendment
Serial No. 10/506,980
Attorney Docket No. 062221

to provide this teaching. In response, Applicants respectfully submit that claim 28 is patentable due to their dependency on independent claim 23, which Applicants submit is patentable for at least the reasons discussed above. Favorable reconsideration is respectfully requested.

Claims 35 and 36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson et al. and Berthon-Jones as applied to claim 23 above and further in view of Estes et al. (US 5,551,418).

It is the position of the Office Action that the combination of Johnson and Berthon-Jones discloses the invention as claimed, with the exception of the specifics of changing blower speed with inspiration and expiration. The Office Action relies on Estes to provide this teaching. In response, Applicants respectfully submit that claims 35 and 36 are patentable due to their indirect dependency on independent claim 23, which Applicants submit is patentable for at least the reasons discussed above. Favorable reconsideration is respectfully requested.

For at least the foregoing reasons, the claimed invention distinguishes over the cited art and defines patentable subject matter. Favorable reconsideration is earnestly solicited.

Should the Examiner deem that any further action by applicants would be desirable to place the application in condition for allowance, the Examiner is encouraged to telephone applicants' undersigned attorney.

Amendment
Serial No. 10/506,980
Attorney Docket No. 062221

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,
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Enclosures: Replacement Drawing Sheets corresponding to Figures 1 and 4-7
Additional Drawing Sheets corresponding to Figures 6(b) and 8
Petition for Extension of Time